UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,037	01/10/2001	David A. Mark	112701-138	3136

29157 7590 10/22/2002

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
SHAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/22/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/759,037	MARK ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The response filed on July 31, 2002 has been entered. Claims 1-22 are pending in this application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:

> The disclaimer fee of $110.00 in accordance with 37 CFR 1.20(d) has not been submitted, nor is there any authorization in the application file to charge a specified Deposit Account or credit card.

3. Claims 1-22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent 5,661,123 ('123), claims 1-22 of US Patent 6,200,950 ('950), claims 1-20 of US Patent 5,549,905 ('905), for the reasons of record.

Claims 1-22 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/622629.

Claim Rejections - 35 USC 102

4. Claims 1-12, 14-20, 22 stand rejected under 35 U.S.C. 102(b) as being anticipated by Henningfield et al US Patent 5,221,668.

Applicant's arguments with respect to this rejection have been fully considered but are found persuasive.

Applicant argues that the preferred caloric density of Henningfield is 1.3 kcal/ml. In response Examiner states that preferred embodiments do not constitute a teaching which is away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 169 USPQ 423 (CCPA 1971). Henningfield discloses liquid nutritional products for trauma and surgery patient has a caloric density of about 1.2 to 1.5 Kcal/ml. Thus, Henningfield anticipates the instant caloric density.

Applicant also states that the protein system of Henningfield is not believed to be the same as hydrolyzed when protein. First, claim 7, is not limited to such language. Second, Examiner stated that protein system of Henningfield contains partially hydrolyzed whey protein such as lactoalbumin, and a calorie nitrogen ratio of about 112:1 to 145:1, wherein the portion of and wherein 18-24% of the calories are provided by proteins, 20-30% are provided by lipids and 50-58% are provided by carbohydrates (see abstract table 1, col 6 lines 25-40, col 9 lines 1-68, col 11, lines 31-42, claims 1, 4, 19 and 22). Thus, Hennigfield is anticipatory with respect to such limitations.

In response to applicant's argument that Henningfield's composition is intended for trauma patients Examiner states that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967). Thus, Henningfield meet the limitations set forth in the instant claims.

Claim Rejections - 35 USC § 103

5. Claims 1-16, 18-22 stand rejected under 35 U.S.C. 103(a) as obvious over Gray et al US Patent 5,714,472.

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

Applicant argues that with respect to the protein energy content of Gray "about 22%" is not the same as "about 20%." In response, Examiner assuming arguendo that such statement is correct in context of Gray's claims and those presently claimed, the rejection is made under the obviouness statute. Gray's components are substantially similar to those instantly claimed. Thus, absence of showing the criticality, it would have been *prima facie* obvious to optimize the concentrations of Gray's compositions by routine experimentation (see 2144.05 II). The ordinary skill in the art would have been motivated to optimize the viscosity of the ~~Evans~~ GRAYS' final formulation, because he would have had a reasonable expectation of success in achieving the desirable clinical outcome by modifying Gray's compositions.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimbo US Patent 5,166,189 in view of Schmidl US Patent 5,504,072, Gray US Patent 5,714,472, and Maubois US Patent 4,427,658 and further in view of Granger et al (JPEN 12:278-281, 1988).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the rejection is based on the combined teachings of Schmidl Gray, Maubois and Granger. Accordingly, all limitations of the instant claims are taught by the combined teachings of the references and the claims stand rejected for the reasons of record.

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ. 33 (C.C.P.A. 1937). In re Russell 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Moreover, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, it is well established in the art that hypermetabolicly stressed patients may suffer from gastrointestinal malabsorption due to the changes of the intestinal mucosa and the intestinal capillary bed; subsequently, said patients experience enhanced protein absorption when a suitable hydrolyzed protein source (such as whey, because of its well balanced aminoacids content). Moreover, Schmidl

states that it is well known in the art that the required caloric density and nitrogen content of the composition can be measured to best fit the needs of critically ill patients (see col 6 lines 2-9). Thus, such modifications are well within ordinary level of a skilled artisan.

The teachings of Gray, Trimbo and Maubois further supplement those of Schmidl. The enteral formulation of Gray meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma, burn or related complications. Gray's formulation has caloric density of at least 1.3 Kcal/ml and comprise a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source that meets U.S. RDAs recommendations of said nutrients (See col 5 lines 25-38, 65-68, and Col 6 lines 35-42, and Col 7, lines 0-14).

Trimbo teaches specific protein requirement for critically ill patients. Trimbo fails to use hydrolyzed whey protein. Maubois et al disclose a method of obtaining hydrolyzed whey protein as well as an enteral nutritional formulation for use in an intensive care setting to the patients who may require a protein intake of the 7-25% of total caloric intake, wherein said protein comprising a hydrolyzed whey protein (see example 5 and 6).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Schmidl's composition to not only contain Beta Carotene, as

suggested by Gray, but also optimize the requisite caloric density and nitrogen intake as taught by Trimbo and Maubois, because one skilled artisan have had a reasonable expectation to improve enteric compositions of Schmidl to best satisfy the need of metabolically stressed patients in a critical care setting.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

ss
October 21, 2002